



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2018-D-0075]

The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products;

Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: Guidance for Industry." The draft guidance, when finalized, will advise food manufacturers of our intent to exercise enforcement discretion related to the use in the Nutrition Facts label of a symbol "†" immediately after the added sugars percent Daily Value information on certain foods. The symbol would lead the reader to truthful and non-misleading statements outside the Nutrition Facts label to provide additional information regarding the added sugars present in particular foods.

DATES: DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to ensure that we consider your comment before we take further action.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-0075 for "The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products:

Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Nutrition and Food Labeling, Nutrition Programs Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance. FOR FURTHER INFORMATION CONTACT: Claudine Kavanaugh, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-1450.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled "The Declaration of Added Sugars on Honey, Maple Syrup and Certain Cranberry Products: Guidance for Industry." We are issuing the draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

The draft guidance is intended to advise food manufacturers of our intent to exercise enforcement discretion related to the use in the Nutrition Facts label of a symbol "†" immediately after the added sugars percent Daily Value information on certain foods. The symbol would lead

the reader to truthful and non-misleading statements outside the Nutrition Facts label to provide additional information regarding the added sugars present in particular foods. The draft guidance would explain that we intend to consider exercising our enforcement discretion for the use of this symbol on single ingredient packages and/or containers of pure honey or pure maple syrup, and certain dried cranberry and cranberry juice products that are sweetened with added sugars, and that contain total sugars at levels no greater than comparable products with endogenous (inherent) sugars, but no added sugars.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

III. Other Issues for Consideration

We invite interested persons to comment on topics related to the draft guidance. However, we are particularly interested in responses to the following questions:

1. The draft guidance is intended to advise food manufacturers of our intent to exercise enforcement discretion related to the use in the Nutrition Facts label of a symbol "†" immediately after the added sugars percent Daily Value information on certain foods. Should we use a different symbol? If so, what symbol should we use and what is the rationale for using an alternative? Also, should the placement or location of the symbol be elsewhere on the Nutrition Facts label? For example, should the symbol appear after "Includes X g Added Sugars" instead? Please explain where the symbol should appear and your reasons for placing the symbol elsewhere on the label.

2. We are considering giving an additional year to come into compliance with the changes required by the final rule for the labeling of packages or containers of pure honey and maple syrup, and for the dried cranberry and cranberry juice products described in this draft guidance. Consumers will likely become more acclimated and educated on having an added sugars declaration on the Nutrition Facts label during this time period, based in part on other products in the marketplace bearing the new Nutrition Facts label. Should FDA consider this period of enforcement discretion given that, in the *Federal Register* of October 2, 2017 (82 FR 45753), FDA has proposed to extend the Nutrition Facts label compliance date from July 26, 2018, to January 1, 2020, for manufacturers with \$10 million or more in annual food sales and from July 26, 2019, to January 1, 2021, for manufacturers with less than \$10 million in annual food sales? Please explain your reasoning.

Dated: February 27, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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